Full Field Digital Mammography (FFDM) Accreditation and Certification Update

Kish Chakrabarti, Ph.D.

- FDA approved GE's Senographe 2000D, an FFDM system, as a new modality in 2000 – hard copy first soft copy added later. Fischer's SenoScan in 2001; LORAD's LDBI in 2002.
- In Absence of FFDM accreditation body, FDA provides approval to use an FFDM system under MQSA by extending SF certificates to cover FFDM systems
- Approval process is briefly summarized

- Until otherwise notified by FDA, an FFDM unit will be exempt from the MQSA accreditation requirement. Until FDA issues such notification, a facility must request FDA to extend its screen-film certification to cover its FFDM units.

- Requests for FFDM certification extension need to supply all the information listed in the document MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography

MQSA FACILITY REQUIREMENTS FOR USE OF FFDM

- Facility Status Information
- FFDM Unit Identification
- Digital Image Receptor Identification
- Identification of Printers for Hard Copy Output
- Monitor Identification (if soft copy display is available)
- Phantom Identification
- Personnel Qualifications

- Phantom Image
- Personnel Information
- Report of Mammography Equipment Evaluation (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the receipt of this letter)
- Manufacturer's Quality Control Program in accordance with 900.12(e)(6)
- Signature of Lead Interpreting Physician

- If a facility receives a Letter of Acceptance, the approved FFDM unit will be added to the facility's certificate.

- The facility must maintain its accreditation status for at least one screen-film unit in order to maintain its certification status when utilizing an FFDM unit.

- The facility is also subject to an annual onsite MQSA inspection of its FFDM unit at the same time its screen-film unit(s) is/are being inspected.

- The FFDM unit must be located within the same inspection jurisdiction as the certified screen film facility. In most cases, this means that the FFDM unit must be located in the same State as the certified screen film facility.

- The lead interpreting physician must oversee the quality assurance programs for both the screen film and off-site FFDM units.

AOP Mode and SNR Check

Exposure Parameter – AOP, STD Mode

Acrylic Thickness (mm)	Target/ Filter	kV	mAs	SNR
25	Mo/Mo	27	20-60	≥ 50
40	Mo/Rh	28	50-100	≥ 50
60	Rh/Rh	32	50-100	≥ 50

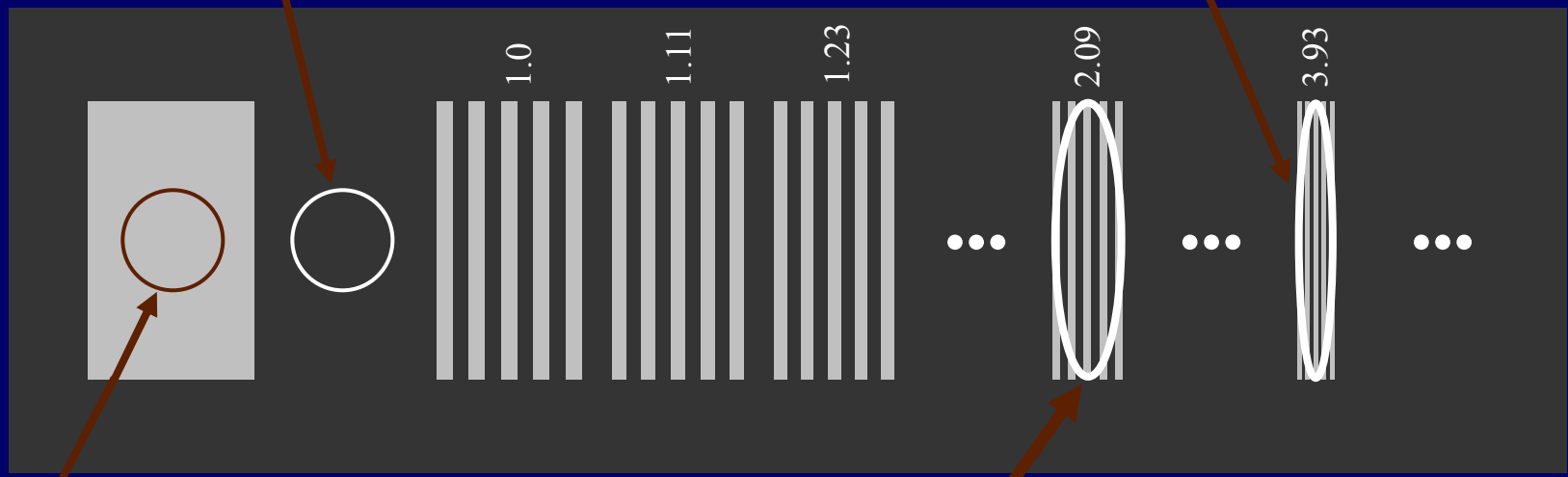
Following tests must be performed on “Raw” images:

- CNR Test
- MTF Measurement
- AOP Mode and SNR Check

MTF by Noise Measurement

Default ROI to measure mean of “bar” material.

Ellipse ROI to measure std. dev. of “4 lp/mm” pattern.



Default ROI to measure mean of “space” material.

Ellipse ROI to measure std. dev. of “2 lp/mm” pattern.

Viewing Conditions Check and Setting

- Analysis of RWS Screen Uniformity
- Room Description
  - *Monitor Position*
  - *Room Lights*
  - *Desk Lights*
  - *Others*
- Ambient Light Value
- Room Layout

Display System QC

New Review Work Station Monitor Calibration

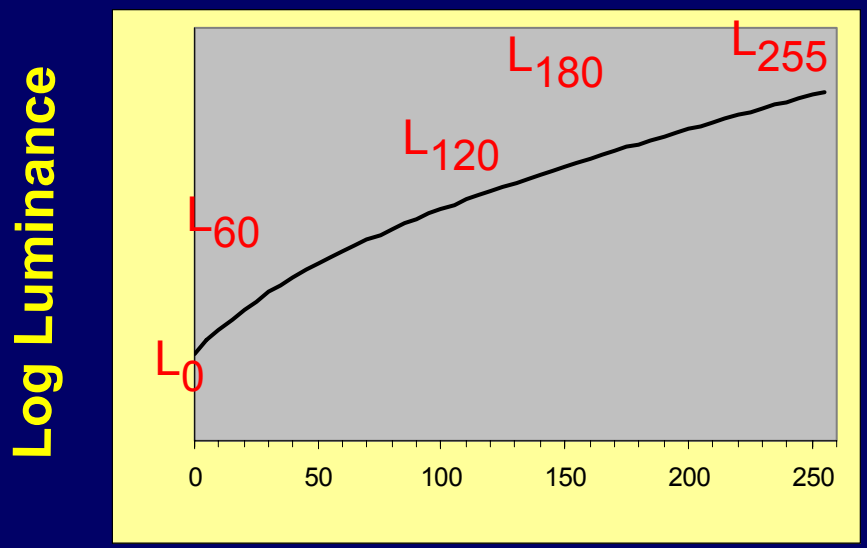
Field Engineer sets black / white levels.
Uses external, calibrated photometer

FE performs perceptual linearization.
Uses DOME photometer

FE records 5 reference luminance levels
Uses DOME photometer

Physicist checks consistency of reference luminance levels

Physicist checks consistency of reference luminance levels

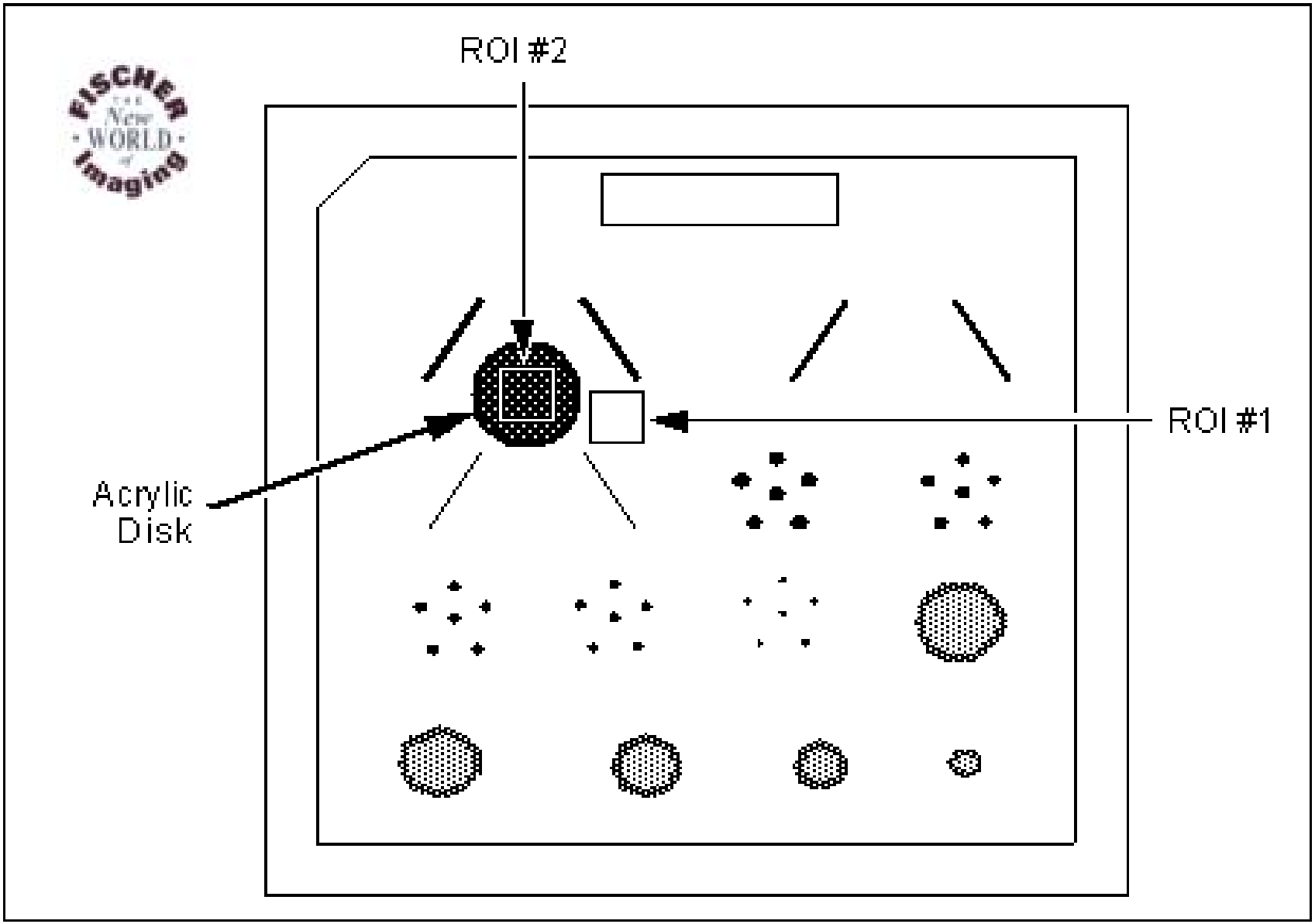


Medical Physicists QC Tests For Fischer SenoScan

Test	Action Limit
Linearity, Reproducibility and Accuracy	Linearity > 0.08 Reproducibility > 0.035
Phantom Image Acquisition Test	Background mean more than ± 100 and Background RMS more than 50 ADU from the Baseline values. Den. Diff more than ± 300 ADU limit
Phantom Image Quality	Less than 4 fibers, 3 speck groups and 3 masses
System Resolution/ Scan Speed Uniformity	< 7 lp/mm in standard mode at any of 3 locations, < 11 lp/mm in High. Res mode

Medical Physicists QC Tests For Fischer SenoScan Tests(Contd.)

Flat Field Test	Mean Deviation between ROI in each corner and center more than $\pm$ 20%
System Artifacts	Artifacts visible in image with a window width of $\geq$ 800
Geometric Distortion and Resolution Uniformity	Obvious distortion and blurring in the image
Image Display	Daily Image Display check requirements not maintained
Viewing Room Illuminance	> 50 lux at screen of either display monitor


ROI #2
ROI #1
Acrylic
Disk